

1. A spacing apparatus for use with a brachytherapy device for treating target tissue surrounding a surgical extraction site, comprising:
  - an insertion member having a proximal end and a distal end;
  - a spacing element disposed on the distal end of the insertion member, the
- 5 spacing element having a predeterminable height and being adapted to position a brachytherapy device disposed within a surgical extraction site at a distance apart from tissue surrounding the surgical extraction site, the distance being equal to the height of the spacing element.
- 10 2. The spacing apparatus of claim 1, wherein the spacing element is movable between a closed position in which the spacing element is disposed adjacent the insertion member, and an open position in which the spacing element extends outward from the insertion member.
- 15 3. The spacing apparatus of claim 2, wherein the spacing element in the open position is effective to position a brachytherapy device disposed within a surgical extraction site at a distance apart from tissue surrounding the surgical extraction site.
- 20 4. The spacing apparatus of claim 3, wherein the spacing element comprises an expandable balloon member disposed on a portion of the insertion member.
- 25 5. The spacing apparatus of claim 4, wherein the expandable balloon member is inflated in the open position, and is deflated in the closed position, wherein the expandable balloon member has a predetermined shape in the open position such that, when inflated, the balloon member is effective to position the brachytherapy device at a predeterminable distance apart from tissue surrounding the surgical extraction site, and wherein the insertion member includes an inner inflation lumen and a port communicating with the lumen and an interior portion of the balloon.

6. The spacing apparatus of claim 5, wherein the predetermined shape of the expandable balloon member is substantially disk-shaped.


5 7. The spacing apparatus of claim 3, wherein the spacing element is formed of a shape memory material and is biased to the open position, and wherein the spacing element has a three-dimensional shape in the open position, and a substantially folded shape in the closed position.

10 8. The spacing apparatus of claim 7, wherein the spacing element is disk-shaped in the open position.

15 9. The spacing apparatus of claim 3, wherein the spacing element is effective to form a radio-opaque barrier between the brachytherapy device and the tissue surrounding the surgical extraction site.

10 10. The spacing apparatus of claim 1, wherein the spacing element is formed integrally with the distal end of the insertion member.

20 11. The spacing apparatus of claim 10, wherein the spacing element is formed of a shape memory material, the spacing member having a first shape in a closed position for inserting the spacing element into a surgical extraction site, and a second shape in an open position, the spacing member being deployable into the open position in the surgical extraction site for positioning the brachytherapy device at a predetermined distance apart from sensitive tissue.

25 12. A brachytherapy device, comprising:   
an insertion member having a proximal end and a distal end;  
an expandable surface member disposed on the distal end of the insertion member and effective to receive a radiation source for treating target tissue surrounding  
30 a surgical extraction site;

a spacing element disposed in conjunction with the insertion member, the spacing element having a predeterminable height and being adapted to position the first expandable balloon member at a distance apart from tissue surrounding the surgical extraction site, the distance being equal to the height of the spacing element.

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13. The brachytherapy device of claim 12, wherein the spacing element is movable between a closed position in which the spacing element is disposed adjacent the insertion member, and an open position in which the spacing element extends outward from the insertion member.

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14. The brachytherapy device of claim 13, wherein the first expandable balloon member, upon inflation, is effective to move the spacing element to the open position.

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15. The brachytherapy device of claim 14, wherein the spacing element in the open position is effective to position the first expandable balloon member at a distance apart from tissue surrounding the surgical extraction site.

16. The brachytherapy device of claim 13, wherein the spacing element comprises a second expandable balloon member.

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17. The brachytherapy device of claim 16, wherein the second expandable balloon member is expanded in the open position, and is deflated in the closed position, and wherein the second expandable balloon member has a predetermined shape in the open position such that, when inflated, the balloon member is effective to position the brachytherapy device at a predeterminable distance apart from tissue surrounding the surgical extraction site.

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18. The brachytherapy device of claim 17, wherein the predetermined shape of the second expandable balloon member is substantially disk-shaped.

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19. A brachytherapy positioning system, comprising:

a brachytherapy device for treating target tissue surrounding a surgical extraction site;

5 a spacing apparatus comprising a spacing element having a predeterminable height and being adapted to position the brachytherapy device at a distance apart from tissue surrounding the surgical extraction site, the distance being equal to the height of the spacing element.

20. The brachytherapy positioning system of claim 19, further comprising an  
10 insertion member having a proximal end and a distal end, the spacing element being disposed on the distal end of the insertion member.

21. The brachytherapy system of claim 20, wherein the spacing element is  
15 movable between a closed position in which the spacing element is disposed adjacent the insertion member, and an open position in which the spacing element extends outward from the insertion member.

22. The spacing apparatus of claim 21, wherein the spacing element in the open  
20 position is effective to position the brachytherapy device at a distance apart from tissue surrounding the surgical extraction site.

23. The spacing apparatus of claim 22, wherein the spacing element comprises  
an expandable balloon member disposed on a portion of the insertion member.

25 24. The spacing apparatus of claim 23, wherein the expandable balloon member is inflated in the open position, and is deflated in the closed position, and wherein the expandable balloon member has a predetermined shape in the open position such that, when inflated, the balloon member is effective to position the brachytherapy device at a predeterminable distance apart from tissue surrounding the surgical extraction site.

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25. The spacing apparatus of claim 24, wherein the predetermined shape of the expandable balloon member is substantially disk-shaped.

5 26. The spacing apparatus of claim 22, wherein the spacing element has a three-dimensional shape in the open position, and a substantially folded shape in the closed position, and wherein the spacing element is formed of a shape memory material and is biased to the open position.

10 27. The spacing apparatus of claim 26, wherein the spacing element is disk-shaped in the open position.

15 28. The spacing apparatus of claim 19, wherein the spacing element is effective to form a radio-opaque barrier between the brachytherapy device and the tissue surrounding the surgical extraction site.

29. The spacing apparatus of claim 20, wherein the spacing element is formed integrally with the distal end of the insertion member.

20 30. The spacing apparatus of claim 29, wherein the spacing element is formed of a shape memory material, the spacing member having a first shape in a closed position for inserting the spacing element into a surgical extraction site, and a second shape in an open position, the spacing member being deployable into the open position in the surgical extraction site for positioning the brachytherapy device at a predetermined distance apart from sensitive tissue.

25 31. A method for positioning a brachytherapy device at a distance apart from sensitive tissue proximate to a surgical extraction site, comprising:

introducing a spacing apparatus into a surgical extraction site, the spacing apparatus having a predeterminable height and being adapted to position a

brachytherapy device at a distance apart from tissue surrounding the surgical extraction site; and

introducing a brachytherapy device into the surgical extraction site, the brachytherapy device being effective for treating target tissue within the surgical extraction site;

positioning the spacing apparatus with respect to the brachytherapy device so as to position the brachytherapy device at a distance apart from sensitive tissue proximate to the surgical extraction site, the distance being equal to the height of the spacing apparatus.

32. The method of claim 31, wherein the spacing apparatus and the brachytherapy device are introduced into a surgical extraction site through a single entrance port extending into the surgical extraction site.

33. The method of claim 32, wherein the spacing apparatus is mated to the brachytherapy device.

34. The method of claim 31, wherein the spacing apparatus is introduced through a first entrance port extending into the surgical extraction site, and the brachytherapy device is introduced through a second entrance port extending into the surgical extraction site.

35. The method of claim 31, wherein the spacing apparatus comprises:  
an insertion member having a proximal end and a distal end; and  
a spacing element being disposed on the distal end of the insertion member, the spacing element having a predeterminable height and being adapted to position the brachytherapy device at a distance apart from tissue surrounding the surgical extraction site, the distance being equal to the height of the spacing element

36. A method for positioning a brachytherapy device at a distance apart from sensitive tissue proximate to a surgical extraction site, comprising:

introducing a brachytherapy device into a surgical extraction site, the brachytherapy device comprising:

5 an insertion member having a proximal end and a distal end,  
a first expandable balloon member disposed on the distal end of the insertion member and effective to receive a radiation source for treating target tissue surrounding a surgical extraction site, and

a spacing element disposed on the insertion member proximal to the first  
10 expandable balloon member, the spacing element having a predeterminable height;  
inflating the first expandable balloon member; and

applying radiation to the surgical extraction site to treat target tissue surrounding the surgical extraction site;

wherein the spacing element is effective to position the first expandable balloon  
15 member at a predeterminable distance apart from sensitive tissue proximate to the surgical extraction site, the distance being equal to the height of the spacing element.

37. A method for positioning a brachytherapy device at a distance apart from sensitive tissue proximate to a surgical extraction site, comprising:

20 resecting a tumor site to create an extraction site;

introducing a brachytherapy device into the extraction site, the brachytherapy device comprising:

an insertion member having a proximal end and a distal end,  
a first expandable balloon member disposed on the distal end of the  
25 insertion member and effective to receive a radiation source for treating target tissue surrounding a surgical extraction site, and

a spacing element disposed on the insertion member proximal to the first  
expandable balloon member, the spacing element having a predeterminable height;  
inflating the first expandable balloon member; and

applying radiation to the extraction site to treat target sensitive tissue  
surrounding the extraction site;

5 wherein the spacing element is effective to position the first expandable balloon  
member at a predeterminable distance apart from sensitive tissue proximate to the  
surgical extraction site, the distance being equal to the height of the spacing element.